



Health Research Authority

NRES Committee London - South East

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11 June 2012

Professor Philip Bath
Division of Stroke Medicine – Research Dept
Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Dear Professor Bath

Study Title: Safety and tolerability of clopidogrel when added to aspirin and dipyridamole in high risk patients with recent ischaemic stroke: a randomised controlled trial

REC reference: 08/H1102/112

Protocol number: 31350

EudraCT number: 2007-006749-42

Amendment number: SA02/12

Amendment date: 31 May 2012

Thank you for submitting the above amendment, which was received on 08 June 2012.

Research Site	Principal Investigator / Local Collaborator
West Hertfordshire Hospital NHS Trust, Vicarage Road, Watford, WD17 2AA	Dr Thurul Attygalle

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. The site-specific assessment for the site(s) will therefore form part of the research governance review. The Site-Specific Information (SSI) Form for the site should be included with the application for R&D approval.

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant NHS/HSC R&D office(s) prior to the study starting at the site.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H1102/112

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'R Bell', with a stylized flourish above the 'B'.

Rachel Bell
Committee Co-ordinator

Email: Rachel.bell@imperial.nhs.uk